IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVOZYMES A/S,

Plaintiff,

v.

GENENCOR INTERNATIONAL, INC. and ENZYME DEVELOPMENT CORPORATION,

Defendants.

C.A. No. 05-160-KAJ

DEFENDANTS' REBUTTAL POST-TRIAL BRIEF

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I. INTRODUCTION AND SUMMARY OF REPLY ARGUMENT

Novozymes' Opposition throws caution, and the true record, to the wind, by relying on distortions of the record and false accusations in lieu of evidence.[1] Why do so? Because:

- *Novozymes cannot meet its burden of proof on infringement* — The alleged "parent" G-ZYME® G997 product is not a "parent *Bacillus stearothermophilus* alpha-amylase," nor does it have a single, unvarying amino acid sequence that could serve as a proper comparator to prove infringement.

- *The '031 Patent is invalid* — Novozymes belatedly attempts to retract its admission of the *prima facie* obviousness of the '031 Patent, but the evidence, including the testimony of Novozymes' own expert, is unequivocal that Suzuki provides motivation and reasonable expectation of success sufficient to render obvious the alleged invention of the '031 Patent. Machius '95 teaches the specific structural basis for the improved thermostability observed by Suzuki, providing yet more motivation and confidence of success to the protein engineer, compelling the conclusion that the '031 Patent is invalid.

- *Novozymes cannot justify its concealment of Machius '95 and misrepresentation of the Borchert data* — Novozymes discards ten years of reliance on Machius '95 to quibble with its teachings. Novozymes tells inconsistent stories about whether it considered disclosing Machius '95. Novozymes cannot "explain away" its failure to call to the Examiner's attention the many biasing variances of the Borchert experiment from Suzuki, and the numerous problems with the data. These end-game rationalizations do not change the fact that Novozymes acted with deceptive intent.

II. SPEZYME® ETHYL DOES NOT INFRINGE PROPERLY CONSTRUED CLAIMS 1, 3, AND 5

There can be no dispute that, based on Genencor's constructions, SPEZYME® Ethyl does not infringe the '031 Patent. Genencor's proper constructions should be adopted.

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[1] For example, Novozymes repeatedly accuses Genencor of "copying" in creating SPEZYME® Ethyl. In fact, SPEZYME® Ethyl was developed and introduced before the '031 Patent issued, so Genencor could not have "copied" it. Novozymes' competing product, Liquozyme SC, did not embody the claims soon to issue, so any "copying" of it would not show infringement. Genencor was inspired by the teachings of another in creating SPEZYME® Ethyl, but that teacher was Suzuki. The *only* evidence of what guided the creation of SPEZYME® Ethyl shows that Genencor was motivated by Suzuki's teaching of the 179-180 deletion. (Crabb, Tr. at 40:9-41:7, A-5040–5041.)

A. **Genencor's Construction of "Parent *Bacillus stearothermophilus* Alpha-amylase" — the Amino Acid Sequence of SEQ ID NO:3 — Is Correct**

Rather than face Genencor's argument that "parent *Bacillus stearothermophilus* alpha-amylase" means "SEQ ID NO: 3," Novozymes attacks a variety of straw men, in the shape of arguments Genencor did not make or that Novozymes mischaracterizes. For example, Genencor's construction is not based on the claims' reference to "using SEQ ID NO:3 for numbering." Rather, it is based on the '031 Patent itself and statements made by Novozymes during prosecution. (GCOR Post-Trial Brief at 5-8.)

Novozymes criticizes Genencor's reliance on exchanges with the Examiner with respect to claims 30-39 for a definition of "parent," because that discussion mentioned "variant," not "parent." (NZ Opp. at 29-30.) Novozymes' criticism is misdirected. As even Novozymes agrees, a "variant" necessarily implies a "parent"; discussion of one sheds light on the other. (Alber, Tr. at 202:8-19, A-5203, 202:23-203:11, A-5203–5204; Arnold, Tr. 140:2-4, A-5141.) (GCOR Opp. at 30-33.) Genencor quoted two paragraphs relied on by Novozymes during prosecution to support the new claims, showing that those paragraphs define "parent" as SEQ ID NO:3. (GCOR Post-Trial Brief at 7; GCOR Opp. at 30-32.) Genencor demonstrated how Novozymes ignored its own statements characterizing the asserted claims during prosecution. (GCOR Opp. at 32-33; FF 135-142; CL 4-7, 12.) None of this was addressed in Novozymes' Opposition.

Novozymes neglects the prosecution history because it shows how Novozymes limited the scope of claims during prosecution to obtain allowance. *See Phillips v. AWH Corp.*, 415 F.3d 1307, 1317 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 1332 (2006). Novozymes' construction fails because it is not proper to advance a narrow construction to obtain a patent and a broad construction to prove infringement. *See Research Plastics, Inc. v. Federal Packaging Corp.*, 421 F.3d 1290, 1295 (Fed. Cir. 2005).

B. **Alternatively, Genencor's Construction of "Parent *Bacillus stearothermophilus* Alpha-amylase" — a 514 or 515 Amino Acid Protein — Is Correct**

(1) Novozymes' Position Ignores the Art and Its Expert's Testimony

Novozymes claims that because years after the 1995 effective filing date a particular *Bacillus stearothermophilus* alpha-amylase in the G-ZYME® G997 commercial product was shown to have a

C-terminal truncation, a protein engineer in 1995 would have expected a "parent *Bacillus stearothermophilus* alpha-amylase" to have such a truncation. The key here is the 1995 effective filing date of the '031 Patent. How could the 2005 sequence information of the alpha-amylase of G-ZYME® G997 have influenced a protein engineer's understanding of a claim term as of 1995? It could not have. *See Schering Corp. v. Amgen Inc.*, 18 F. Supp. 2d 372, 380 (D. Del. 1998), *aff'd,* 222 F.3d 1347, 1353-54 (Fed. Cir. 2000). In contrast, the literature relied on by Genencor to establish the art-recognized definition of "*Bacillus stearothermophilus* alpha-amylase" was publicly available in 1995.[2]

Novozymes claims that there was no evidence supporting Dr. Alber's opinion that as of 1995 a protein engineer would have concluded that wild type (*see* FF 167) *Bacillus stearothermophilus* alpha-amylases had 514 or 515 amino acids because the entire proteins were not sequenced and "imprecise" molecular weight gels were run. (NZ Opp. at 32-33.) In fact, molecular weights of "actually produced" proteins were determined on gels to correspond to a protein of 514 or 515 amino acids; molecular weights obtained on such gels were accepted as accurate and relied on by Novozymes' own Dr. Jorgensen in his submissions to this Court. (GCOR Opp. at 34-36, nn.13, 14; FF 155-158.)

In sum, a protein engineer would only consider an alpha-amylase having 514 or 515 amino acids to be the "parent *Bacillus stearothermophilus* alpha-amylase" of the '031 Patent.[3]

(2) G-ZYME® G997 Is Not a "Parent *Bacillus stearothermophilus* Alpha-amylase"

Novozymes argues that it "is the right thing to do" to compare an industrially-produced variant alpha-amylase to an industrially-produced alleged parent in evaluating infringement, but points to nothing

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[2] Dr. Alber reviewed all of the literature. (Alber, Tr. at 208:18-24, A-5209, 215:3-12, A-5216.) Dr. Arnold, agreed with Dr. Alber: she testified that as of 1995 a protein engineer would have considered an alpha-amylase actually expressed from a wild type *Bacillus stearothermophilus* gene to have 514 or 515 amino acids (Arnold, Tr. at 180:1-6, A-5181), and that there was no evidence in the published literature of any alpha-amylase actually expressed from a wild type *Bacillus stearothermophilus* gene that was truncated at its C-terminus. (Arnold, Tr. at 180:7-12, A-5181.) Novozymes had every opportunity at trial to bring other literature to the attention of this Court, if any existed; it did not do so.

[3] Novozymes refers to "other exemplary BSG parents." (TE 100, at 11, col. 1:41-62, A-7011.) (NZ Opp. at 32.) That portion of the '031 Patent recites multiple definitions of "parent alpha-amylase," not "*Bacillus stearothermophilus* alpha-amylase," so it does not contradict that wild type *Bacillus stearothermophilus* alpha-amylases have 514 or 515 amino acids.

in the '031 Patent or file history to support that contention. Nor do the claims specify use of "industrial-production" conditions to evaluate infringement (Novozymes argues elsewhere that how an alleged infringing product is made is immaterial to infringement). (NZ Opp. at 40, ¶ 1.) While SPEZYME® Ethyl and G-ZYME® G997 are both produced under "industrial conditions," Novozymes ignores the fact that the alleged "one-to-one" comparison cannot be made, because SPEZYME® Ethyl is produced in *Bacillus licheniformis* while G-ZYME® G997 is produced in *Bacillus stearothermophilus*. (TE 161, at 1, A-8365.) Novozymes tries to gloss over the differences caused by expression in different host organisms, but those differences show that G-ZYME® G997 cannot be a "parent."[4]

Novozymes further misrepresents the record in saying that "Genencor's work, and experiments by Dr. Jorgensen from Novozymes, show that G997 and SPEZYME® Ethyl have the same post-translational truncation at the C-terminus." This is refuted by Dr. Alber's uncontroverted testimony, supported by the pre-litigation Chang analysis,[5] that G-ZYME® G997 is a mixture at least of truncated proteins having 27, 28, or 29 amino acids truncated from the C-terminus. (GCOR Opp. at 36.) Despite Novozymes' contention (NZ Opp. at 34-35), there is no one, consistent sequence for G-ZYME® G997 proved on the trial record — all evidence is to the contrary. The industrial process that results in such multiple truncations has altered the true wild type alpha-amylase produced from the wild type gene of *Bacillus stearothermophilus* strain G997. (GCOR Opp. at 36; FF 172-177.)

To hedge its bet, Novozymes argues that "even if G997 came in three versions," that does not "disqualify" G-ZYME® G997 from serving as a *Bacillus stearothermophilus* alpha-amylase of the claims. (NZ Opp. at 35.) Novozymes now argues that SPEZYME® Ethyl must be compared to the so-called

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[4] This is shown by Dr. Jorgensen, actually. His work shows that if one expresses an alpha-amylase from the same *Bacillus stearothermophilus* alpha-amylase gene in different *Bacillus* strains, the ultimate fermentation product proteins can vary at the C-terminus. (Jorgensen, Tr. at 663:8-19, A-6071, 664:9-11, A-6072; Alber, Tr. at 229:7-230:4, A-5230–5231, 230:20-231:4, A-5231–5232; TE 135, A-8357–8358; TE 161, A-8365–8374.) (FF 179-181.)

[5] Novozymes points to the Chang memo (TE 161, A-8365–8374), where Ms. Chang discussed both SPEZYME® Ethyl and G-ZYME® G997. While that may be true, she most emphatically did not do so to evaluate infringement — the '031 Patent had not issued at the time she wrote the memo.

"preponderant consensus sequence," a term that never saw the light of day at trial. Whoever heard of such a thing: evaluate infringement based on the preponderant (whatever that means) consensus (as determined by whom, the patentee? as of what date, 1995? 2005?) alpha-amylase floating around in an undefined mixture of alpha-amylases contained in a commercial product, made under unspecified industrial conditions not in evidence? No wonder Novozymes offered no evidence or opinion on the "preponderant" theory at trial.

Novozymes last claims that SPEZYME® Ethyl should be compared to every alpha-amylase floating around in Genencor's G-ZYME® G997 commercial product (there were at least three shown in the trial record). (NZ Opp. at 35.) While that "covers all bases," it proves invalidity of the '031 Patent. If the claims truly require a comparison of an accused product to all alpha-amylases floating about in unspecified samples of an alleged parent product, they do not provide notice of what does and what does not infringe, and are invalid as hopelessly vague and indefinite. (GCOR Opp. at 34.)

C. Genencor's Construction of "% Homology" — Requiring Counting Amino Acids of Gap Regions — Is Correct

The '031 Patent cites to the GAP (GCG) program as a suitable method to align two amino acid sequences, from which the % homology is "revealed" (to use the exact word of the '031 Patent). (TE 100 at 9, 4:39-41, A-7009.) (GCOR Post-Trial Brief at 12.) There is no explicit description of how to calculate % homology based on the alignment. (FF 191.) Novozymes seeks to impose a construction that would account only for substitutions, criticizing Genencor for considering other parts of the '031 Patent that treat deletions and insertions as equally important as substitutions. Given that the hallmark sequence change of the claimed invention is the 179-180 deletion, a protein engineer would consider Novozymes' construction — "count what matches" as opposed to "count what matters" — ridiculous.

There are many other deficiencies in Novozymes' analysis:

- Novozymes criticizes Genencor for looking to the definitions of "variant" in the '031 Patent to clarify whether deletions should be counted in computing % homology. (NZ Opp. at 36-37.) Because deletions, insertions, and substitutions are discussed in the '031 Patent in the context of

sequence differences between a variant and its parent, one must consider the meaning of "variant" in this exercise. (GCOR Post-Trial Brief at 13-14; FF 201-212.) Novozymes' accusation that Genencor relies on the specification's description of "variant" to construe % homology "in order to confuse the issue" is entirely unwarranted.[6]

- Novozymes' double-speak cannot explain away Dr. Arnold's admission (quoted in Genencor's Opposition at 39) that in determining % homology in the earlier litigation (based on the same patent specification) she did take into account insertions, substitutions, and deletions. (Arnold, Tr. at 185:7-21, A-5196.) (FF 207.)
- Novozymes would rely on what it claims is the "industry standard," using the GAP (GCG) program to "count what matches," *i.e.*, ignore deleted amino acids of gap regions. (NZ Opp. at 38.) Novozymes provides no citation to the record to support this alleged "industry standard" for computing % homology, nor to any support in the patent itself. Genencor's 2004 patent application does list GAP (GCG) among other programs, but is irrelevant to claim construction here. *See Schering Corp.*, 18 F. Supp. 2d at 380.

Contrary to Novozymes' characterization, Genencor does not argue that other programs, such as the Align or GAP (Huang) programs, or "by hand" calculations, must be used to the exclusion of GAP (GCG). (NZ Opp. at 38.) One may also use the "modified GAP (GCG) method" to calculate % homology, which does utilize GAP (GCG). (GCOR Post-Trial Brief at 15-16; FF 200, 216.) Or, one could use the GAP (GCG) to align the variant and parent sequences, for which the '031 Patent cites it. (GCOR Post-Trial Brief at 15.)

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[6] Novozymes forgets that "[t]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Phillips* 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). In *Lava Trading, Inc. v. Sonic Trading Mgmt., LLC*, No. 05-1177, 2006 WL 1008842, at *5 (Fed. Cir. Apr. 19, 2006), the Court arrived at the meaning of a claim term by considering the claim language and the embodiments in the specification, stating: "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification" (quoting *Phillips*, 415 F.3d at 1313).

Genencor's construction of % homology, which accounts for the amino acids of gap regions in comparing a variant to its parent, should prevail. Novozymes has failed to prove that GAP (GCG) alone is the only method that "may be suitably used" to calculate % homology in the '031 Patent.

III. NOVOZYMES CANNOT AVOID THE ADMITTED OBVIOUSNESS OF THE '031 PATENT — CLAIMS 1, 3, AND 5 ARE INVALID

A. Suzuki Makes the Invention Obvious and Machius '95 Provides Increased Motivation to Make the Claimed Invention

Novozymes' distortion of the facts and the law do not obscure what is clear — Suzuki and the Bisgard-Frantzen PCT render the claimed invention *prima facie* obvious, and Machius '95 provides even more certainty that the 179-180 deletion would increase the thermostability of BSG. Any supposed "unexpected results" or other secondary evidence of nonobviousness do not overcome the strong primary evidence of obviousness. (GCOR Post-Trial Brief at 21-26; GCOR Opp. at 1-8.)

(1) Novozymes' Untimely Attempt to Retract Its Admission of *Prima Facie* Obviousness Fails

Novozymes asserts for the first time in its Opposition that Suzuki and the Bisgard-Frantzen PCT do not establish *prima facie* obviousness. (NZ Opp. at 21.) Novozymes never took this position during prosecution or at trial. No wonder — the evidence Novozymes cites in "support" proves just the opposite. "Reasonable expectation of success" is found when the prior art provides specific rather than just general guidance. (GCOR Opp. at 5-6, citing *In re O'Farrell,* 853 F.2d 894, 903-904 (Fed. Cir. 1988); *Medichem, S.A. v. Rolabo, S.L.,* 437 F.3d 1157, 1166-67 (Fed. Cir. 2006).) Novozymes admits that Dr. Arnold herself testified that Suzuki provides the impetus to make the 179-180 deletion in BSG (NZ Opp. at 21, citing Arnold, Tr. at 742:9-12, A-6530), and Dr. Zeikus agreed. (Zeikus, Tr. at 699:2-4, A-6107.) (FF 167; CL 48.) Suzuki provides specific guidance and a "reasonable expectation of success."

Dr. Arnold's testimony (that one would not know for certain what the result would be without doing the experiment), and Dr. Zeikus' testimony (that Suzuki provides a 50/50 chance of the 179-180 deletion increasing the stability in BSG), do not contradict the "reasonable expectation of success." (NZ Opp. at 21, citing Arnold, Tr. at 742:9-12, A-6530 and Zeikus, Tr. at 699:8-12, A-6107.) "Absolute

predictability" is not required; "reasonable expectation of success" is found even in view of contradictory teachings in the art suggesting that the invention would work only "sometimes." *Medichem*, 437 F.3d at 1165-67. (GCOR Opp. at 5-8.)

(2) Novozymes' Attempt to Confuse the Teachings of Machius '95 and Suzuki Fails

After arguing that Suzuki does not predict success, Novozymes then does an about-face and argues that Suzuki provides such "complete" motivation that Machius '95 is irrelevant. (NZ Opp. at 24-25.) This argument manages to both contradict Novozymes' position that Suzuki does not make the invention *prima facie* obvious, and to be at odds with the evidence of record. Unequivocally, Machius '95 teaches that Suzuki Region I is in a surface loop and that the additional two residues in BAN as compared to BLA explain the decreased thermostability of BAN (TE 173 at 553, A-8384), providing critical additional motivation. (FF 71-74.) As Dr. Machius explained:

> The way I see it is that after Suzuki published his study, there was motivation to make the deletion in BSG. However, Suzuki put forth a hypothesis about the presence of specific interactions in the Suzuki region. And as Dr. Arnold just testified very nicely, proteins are very intricate objects. They have a lot of interactions when you change the mutant residues that are involved in these interactions.
>
> The chances that protein gets worse are much higher than it gets better. So that would...be a concern to a biochemist to make that mutation in BSG. That is why the notion that the Suzuki region is in a loop is so important and that is what we concluded from our '95 paper.
>
> Loops are loops because they do not have many interactions, if they have any interactions at all. So a biochemist would have realized this immediately and would have been immediately much more motivated to make the deletion in BSG. So at that point, I would consider making the deletion a no brainer. (Machius, Tr. at 774:3-22, A-6562.)[7]

Novozymes diverts attention from this clear and specific teaching by co-mingling the particular explanation for the results that Suzuki observed with theories about the underlying structural bases for greater thermostability of BLA. (GCOR Opp. at 2-4.) As Dr. Arnold said, there may have been uncertainty regarding the mechanism making BLA more thermostable than BAN. (Arnold, Tr. at 735:14-

[7] Novozymes continues in its Opposition Brief to attribute its own counsel's words to Dr. Machius. Novozymes' seeming explicit "quote" notwithstanding (*see* NZ Opp. at 21-22, 24), Dr. Machius did not testify that one of ordinary skill could not have predicted "if there was any stabilization at all" — this was part of the question to him. (GCOR Opp. at 6.)

17, A-6523.) However, this lack of certainty did not extend to the statement in Machius '95 that Suzuki Region I is in a surface loop. A protein engineer would have understood that statement as distinct from the more general theories set forth in Machius '95, because it is a specific structural explanation for an actual experimental result. (Machius, Tr. at 784:7-21, A-6572.)

Novozymes' pre-litigation conduct shows there was no confusion. Until this case, Novozymes was not confused by the teachings of Machius '95 — it relied on those teachings in its publications and submissions to the PTO (even as "crystal balls" into the structure of BSG). (TE 102 at 9100, A-8148; TE 665 at NV-0094701, A-9065.) (GCOR Post-Trial Brief at 30; GCOR Opp. at 2; FF 86-92; CL 91-92.)

(3) Machius '95 Was Highly Relevant to the '031 Patent

Novozymes asserts that Machius '95 does not address the problem posed by the '031 Patent. This is just not true. The primary purpose of Machius '95 was, obviously, determining the three-dimensional structure of BLA. But, Machius '95 expressly acknowledges that because *Bacillus* alpha-amylases are industrially important enzymes often used in contexts requiring stability at high temperature, the molecular mechanisms of their thermoinactivation have been studied (implicitly, to engineer more thermostable enzymes). (TE 173 at 551, A-8382.) As Dr. Machius explained, protein engineering and structural biology are overlapping areas; protein engineers use structural biology to design proteins by analyzing three-dimensional structures and drawing conclusions from them. (Machius, Tr. at 467:10-20, A-5698.) Machius '95 did not need to disclose any new alpha-amylase variants (as argued in Novozymes' Opposition at 25) — Suzuki had already made and tested them. Machius '95 provides the three-dimensional structural information about those variants that protein engineers rely upon in identifying and evaluating insertions, substitutions, or deletions to be made in engineering a protein. (Machius, Tr. at 467:10-20, A-5698.) (FF 60, 77-82; CL 71.) Machius '95 is just the sort of art to which protein engineers would have looked in designing BSG enzymes with increased thermostability.

Machius '95 increased the confidence a protein engineer would have had in 1995 that the 179-180 deletion would stabilize BSG. As such, Machius '95 supplies additional motivation not found in Suzuki and provides even stronger primary evidence of obviousness.

B. Irrelevant "Secondary Considerations" Do Not Outweigh Primary Evidence of Obviousness

Novozymes argues that its evidence of secondary considerations, *i.e.*, supposed unexpected results, commercial success, etc., should trump the primary evidence of obviousness. This argument fits neither the law nor the facts here.

The allegedly "unexpected" results presented were not a proper comparison to Suzuki, even though that comparison was the only alleged basis for patentability. (*See* § V.B.2, *infra*.) And, even when taken at face value, the "unexpected results" were not surprising. (GCOR Post-Trial Brief at 21-22; GCOR Opp. at 8-9; FF 132-134; CL 53.)[8] That the precise quantitative degree of improvement (which varies according to the assay conditions, as evidenced by the difference between Suzuki's and Dr. Borchert's results with BAN (Klibanov, Tr. at 589:20-590:3, A-5820–5821)), cannot be predicted is of no moment here. *See In re Longi,* 759 F.2d 887, 896 (Fed. Cir. 1985). (GCOR Post-Trial Brief at 21-22; GCOR Opp. at 9; FF 132-134; CL 53, 101.) Protein engineers in 1995 would have expected an improvement within an order of magnitude of what Suzuki observed; the improvement Dr. Borchert reported falls within the range of those expectations. Simply put—the results were not surprising.[9]

Novozymes cites to *In re Soni*, 54 F.3d 746 (Fed. Cir. 1995), for the proposition that unexpected results "will preclude obviousness." (NZ Opp. at 22). However, nowhere in *Soni* does the court make such a statement; the *Soni* decision relates to what factual evidence is necessary to prove unexpected results. *Soni*, 54 F.3d at 750-51. In *Richardson-Vicks, Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997), the court confirmed that *Soni* merely "reiterated the well-established rule that all evidence of

[8] Novozymes alleges that Dr. Klibanov's conclusion to this effect was unsubstantiated. (NZ Opp. at 23). Dr. Klibanov based his conclusion upon his considerable experience and expertise and the fact that Suzuki reports an increase of 25-fold upon making the deletion in BAN. (Klibanov, Tr. at 586:15-590:6, A-5817-5821.) (GCOR Opp. at 8-9.)

[9] Novozymes' own expert did not disagree: Dr. Arnold argued at length about the unpredictable nature of making the Suzuki deletion in BSG and ardently touted the industrial benefits of BSG del evident from the Borchert Declaration. (Arnold, Tr. at 746:19-747:4, A-6534–6535, 762:16-22, A-6550.) Yet, in the face of Dr. Klibanov's testimony, she never once said that the results were surprising or unexpected. Dr. Arnold's marked silence about this issue is as damning to Novozymes as an admission that Dr. Borchert's results are neither surprising or unexpected.

obviousness must be considered," including secondary considerations such as unexpected results, but explained that secondary considerations are but a part of the totality of the evidence. The court further cautioned that "the existence of such evidence, however, does not control the obviousness determination." *Id.* (emphasis added). (GCOR Opp. at 9-11; CL 46.) Secondary considerations are not, as Novozymes would have the court believe, *per se* determinative of non-obviousness. *Soni* certainly does not so hold.

Richardson-Vicks is precisely on point and not distinguishable. Novozymes incorrectly characterizes the case as one where the "result" was a predictable affect. (NZ Opp. at 25.) But, in *Richardson-Vicks,* even the defendants agreed that the results were unexpected. *Richardson-Vicks*, 122 F.3d at 1482. The *Richardson-Vicks* court held that the unequivocal evidence of unexpected results did not outweigh the primary evidence of obviousness. *Id.* at 1484.[10]

IV. THE '031 PATENT DOES NOT TEACH A PROTEIN ENGINEER HOW TO MAKE MORE THAN A FEW VARIANTS COVERED BY CLAIMS 1 AND 3, WHICH ARE INVALID AS NOT ENABLED

Novozymes fails even to address, let alone attempt to distinguish, the most factually similar case on enablement for a generic claim, *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212-14 (Fed. Cir. 1991), nor does it discuss *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). (*See* GCOR Post-Trial Brief at 26-27.) These cases demonstrate that, given the many possible changes that may be made to a "starting" molecule (here, SEQ ID NO:3) and the uncertainty as to which changes would provide compounds with activity (or utility), more is required in a patent specification than a handful of variants of uncertain activity. As in *Amgen*, the '031 Patent identifies only a few examples of sequence changes that *might* provide variants with alpha-amylase activity — clearly not enough to support generic claims potentially having billions of molecules within their scope, as is the case for claims 1 and 3.

Novozymes does not contest the astronomical number of variants within the claims. (NZ Opp. at 26-27.) Rather, it declares that "[t]he protein engineer would generally make the fewest alterations that

[10]Novozymes cites to evidence of other objective considerations of nonobviousness. (NZ Opp. at 26.) Suffice it to say that Novozymes has not met its burden to prove that these secondary considerations have the required nexus with the advantages of the claimed invention. (GCOR Opp. at 9-12.)

do the job" and "had ample guidance in the literature about what to conserve and what might usefully [be] changed." (NZ Opp. at 26-27.)[11] The issue is *not*, however, whether a few additional variants within the claims could be discovered upon making the fewest changes, but whether a sufficient number is described so as to enable a protein engineer to practice the full scope of those generic claims without undue experimentation. *See In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991); *Fisher*, 427 F.2d at 836. Novozymes has not pointed to teachings in the '031 Patent that would enable a protein engineer to do so.

Novozymes points to Genencor's 2004 application to bootstrap enablement of the '031 Patent based on what Genencor claimed. Genencor's application cannot be used to enable Novozymes' claims, because the '031 Patent application must satisfy the enablement requirement on its own merits. *See Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). (And, a post-filing date publication, like Genencor's patent application, which published in 2006, cannot supply the enabling disclosure missing in Novozymes' '031 Patent. *See In re Glass*, 492 F.2d 1228, 1232 (C.C.P.A. 1974).)

Claims 1 and 3 of the '031 Patent are not enabled and are, as a result, invalid.

V. NOVOZYMES COMMITTED INEQUITABLE CONDUCT IN PROSECUTION OF THE '031 PATENT, RENDERING IT UNENFORCEABLE

A. Novozymes' "Defenses" Are Based on Misrepresentation of the Evidence

Unable to rebut Dr. Klibanov's evidence regarding the misleading and unreliable Borchert Declaration, Novozymes stoops to distortions of his trial testimony to besmirch his credibility. Specifically, Novozymes relies on an exchange between Dr. Klibanov and counsel for Novozymes regarding an illustrative diagram to accuse Dr. Klibanov of fabricating data (NZ Opp. at 19):

[11] Novozymes' declarations are totally unsupported in the record. As for "mak[ing] the fewest changes," Novozymes cites to testimony of Dr. Arnold that says nothing of the kind. None of Novozymes' citations support the claim that one skilled in the art would make the fewest changes that do the job. On "ample guidance in the literature," Novozymes cites to several portions of the transcript and exhibits, which, at best, describe the tools necessary to measure alpha-amylase activity and make the 179-180 deletion in the alpha-amylase gene. None of those citations describes which amino acids should be deleted or inserted or, in the case of substitutions, which amino acid should be substituted for which original one. Novozymes is making up the evidence it needs as it goes along here.

Q: What specific data are you plotting here?

A: Well, the point of this is simply to show that the failure to account for the ramp-up period, which is the curve to the right will demonstrably result in a longer half life. That is the point of the upper portion of this slide. *These are some arbitrary data, because as I said the only point is to simply demonstrate that the half life when there is no ramp-up appear or that somehow it's taken into account would be shorter than when there is a ramp-up period and it's not taken into account.* The second portion, the lower portion of the slide specifically talks about BAN wild-type enzyme.

Q: Doctor, I just wanted to be clear. I think there is some confusion in the record. There is fictitious, made up data. This is not real data from this case; correct?

A: The data points, you mean.

Q: Yes.

A. *Yes. As I said, these are just representative arbitrary data to illustrate the point that I just made.*

(Klibanov, Tr. at 605:18-606:23, A-6013–6014 (emphasis added).) Novozymes clams this shows "fabricated" data. That is not true.

Dr. Klibanov made it clear he was using a demonstrative to illustrate a point in his direct testimony. Dr. Klibanov's ultimate opinion, that the Borchert experiment conditions, which failed to account for ramp-up, resulted in a markedly inflated half-life for BAN WT, was based on the actual data of the Borchert experiment, as Dr. Arnold admitted[12] and as was reflected in an exchange with the Court:

Q: All I'm trying to ask without creating a new data set, *using the old data set as to which you pointed* and said, to which you pointed and said there was an error because as to BSG, six data points were eliminated which should have been included. *Did anybody sit down and do the calculating that you sophisticated science folks can go and say if I put those six back in this is what the numbers come out at?*

A: *The answer to this question is yes. In fact, I did it myself and, moreover, I presented it, my first expert report in this case.* And basically what I concluded in that expert report was that the data obtained by Novozymes were unreliable, *but if I were to take the data at the face value and treat them more or less correctly, given the limitations of the data,* then the difference in improvement in BSG versus BAN was way under a factor of two.

[12] Novozymes cites to the testimony of Dr. Arnold (Arnold, Tr. at 764:25-765:22, A-6552–6553) to buttress its accusation that Dr. Klibanov manufactured data. Even a cursory reading of the cited portion of Dr. Arnold's testimony, however, makes it clear that she did not accuse Dr. Klibanov of concocting data, but noted that he "made an assumption" (Arnold, Tr. at 765:4, A-6553) in his expert report that allowed him to calculate a corrected half-life for BAN WT "*based on Dr. Borchert's data.*" (Arnold, Tr. at 765:19-20, A-6553 (emphasis added).)

(Klibanov, Tr. at 609:19-610:11, A-6017–6018 (emphasis added).)

Having procured the '031 Patent by misleading the Examiner, Novozymes now continues the same tactics in attempting to enforce the '031 Patent against Genencor.

B. Novozymes Made Material Misrepresentations In and Concerning the Borchert Declaration

(1) Novozymes Misrepresented the Alleged "Unexpected" Nature of the Results

While in a vacuum (and to a layperson) a 63-fold increase might seem a "very significant increase" (Klibanov, Tr. at 601:8-9, A-6009), that number is unsurprising (to one of ordinary skill in the art) compared to Suzuki's 25-fold increase. (Klibanov, Tr. at 545:15-548:22, A-5776–5779, 600:19-601:1, A-6008–6009.) Suzuki's 25-fold improvement, not explicitly stated by Suzuki, but evident from Figures 1 and 5 (TE 115 at Fig. 1, A-8234 and Fig. 5, A-8237), may have been overlooked by the Examiner in allowing the '031 Patent, but this was no excuse for Dr. Borchert's representation that his experiment evidenced "very surprising" and "unexpected" results. (TE 508 at ¶ 9, A-8861–8862.) And, in reality, the relative improvement in BSG over BAN was at most 2- to 3-fold, far less than Dr. Borchert's claimed 5.7-fold. (GCOR Opp. at 19 and 21; FF 116-120; CL 101.) The "unexpected" results were not unexpected at all, despite Novozymes' misrepresentations to the PTO.

(2) The Conditions of the Borchert Experiment vs. Suzuki.

Novozymes chose to base the sole argument for allowance of the asserted claims on a comparison to Suzuki, even though the Suzuki rejection was no longer pending. It surely would have mattered to the Examiner that Novozymes chose conditions different from Suzuki that biased the "experiment" in Novozymes' favor. *See* MPEP § 716.02(b) (applicants have burden to explain data offered to show non-obviousness); *In re Multidistrict Litig. Involving Frost Patent*, 540 F.2d 601, 611 (3rd Cir. 1976) ("Therefore, in submitting evidence of comparative tests, unless the circumstances indicate the contrary, an applicant must be held to be representing that his showing includes a fair and accurate demonstration of the closest prior art of which he is aware.") (citation omitted). (GCOR Opp. at 24-26.)

Novozymes' choice of conditions made all the difference to the "experiment." Relative stabilities of two different enzymes can drastically differ under varying experimental conditions. (*See e.g.*, TE 116 at 3088, A-8241 ("Concluding Remarks").)[13] Having chosen conditions that gave an unreliable half-life for BAN WT and exaggerated the relative improvement in BSG over BAN as a result of the Suzuki deletion, it was incumbent on Novozymes to explain how the experiment differed from Suzuki to allow the Examiner to make a fair assessment of the alleged unexpected results.

The cases Novozymes cites regarding testing conditions are unavailing. The claimed invention in *Merchant* was directed to an industrial method for removing hydrogen fluoride (HF) contaminant from gaseous hydrogen chloride. *See In re Merchant*, 575 F.2d 865, 866 (C.C.P.A. 1978). The claimed method varied from the prior art method by the solid used to absorb the HF contaminant, and the applicant put forth results demonstrating unexpected efficiencies to his method. *See id.* at 867. *Merchant* compared two commercial processes to establish that one is more efficient than the other. *See id.* at 869. In contrast, Dr. Borchert's experiment compared the improvement in an industrial enzyme (BSG) to a non-industrial enzyme (BAN), without having established that BAN is suitable for industrial testing.

Application of Snoddy (420 F.2d 381 (C.C.P.A. 1970)) is no more helpful to Novozymes. Snoddy's claims to a detergent were subject to a *prima facie* obviousness rejection over prior art detergents, which Snoddy was able to overcome by results of comparative testing showing unpredictably superior performance in cooler water than standard, commonly used prior art detergents. *Snoddy*, 420 F.2d at 383. Snoddy compared his claimed detergents in commercial compositions with preexisting commercial prior art detergents. *See id.* Again, Dr. Borchert compared BSG, an industrial enzyme, with BAN, a non-industrial enzyme, under allegedly (but unproven) industrially-relevant conditions, rather than those of the Suzuki experiment against which Dr. Borchert claimed "unexpected" results.

Novozymes advocates a "problem-solution approach" (NZ Opp. at 16), relying on *In re Dillon*, 892 F.2d 1554 (Fed. Cir. 1989). That opinion was *withdrawn* by an *en banc* panel in *In re Dillon*, 919

[13] For example, under the different experimental conditions employed in TE 116, the relative stabilities of BAN and BSG differed from 3-fold to 68-fold. (TE 116 at 3088-3090, A-8241–8243.)

F.2d 688, 690 n.1 (Fed. Cir. 1990). Tellingly, the *en banc* court found that the comparative testing did not provide evidence of unexpected results when considering "*all the evidence of the properties of the claimed invention as a whole, compared with those of the prior art.*" *Id.* at 694 (emphasis added).

Novozymes also asserts that the use of 0.1 mM calcium in the Borchert experiment was suitable because the '031 Patent "discloses 0.1 mM calcium, and a stated object of the invention is to provide a less calcium dependent enzyme," (NZ Opp. at 17), and the Bisgard-Frantzen PCT discloses 0.1 mM calcium, so "an appropriate calcium level from the art *was* used." (NZ Opp. at 17.) Novozymes is cherry-picking and using out of context information that suits its purpose. The '031 Patent does not teach the use of 0.1 mM calcium for the heating phase of a thermal inactivation assay. (GCOR Opp. at 18.) Calcium-independence as a feature specific to the 179-180 deletion (as opposed to the myriad of other mutations disclosed in the '031 Patent) was never argued during prosecution as evidence of nonobviousness, and is merely an afterthought by Novozymes, drummed up for the purpose of excusing Dr. Borchert's biased experiment. Similarly, Novozymes' reliance on the Bisgard-Frantzen PCT is misplaced, because the Examiner was not asked to allow claims based on a comparison to the PCT; it was the Suzuki conditions that mattered. And, the Bisgard-Frantzen PCT teaches the use of 0.1mM calcium for a different assay and a different enzyme than those at issue in the Borchert Declaration.

Despite Novozymes' complaint that Genencor unfairly requires a comparison to Suzuki (NZ Opp. at 15), Suzuki's conditions were not merely "of academic interest" (NZ Opp. at 16); they were conditions that allowed the half-life of BAN WT to be measured reliably, in contrast to Novozymes' own studies that demonstrate half-lives for BAN WT varying over 100% (0.435 – 0.9 minutes) (TE 508 at ¶ 9, A-8861–8862), largely due to the ramp-up problem. (FF 108-115.)[14] The Suzuki conditions were conditions of

[14] Novozymes' response to the ramp-up issue is that "[t]he alleged problem of ramp-up time would not have materially closed the gap or made a difference either." (NZ Opp. at 19.) Novozymes relies on Dr. Arnold's conclusions from recent experiments by Novozymes comparing the thermal denaturation of BAN WT with and without preheated buffer. (NZ Opp. at 19 n.6.) Novozymes has not established that these experiments were performed in the same manner and with the same equipment as used in the Borchert experiment, nor can Novozymes rebut the undeniable conclusion that these experiments, which demonstrate an 0.435-minute half-life for BAN WT (FF 112), are proof of the unreliability of the vastly exaggerated BAN WT half-life calculation in the Borchert Declaration.

the prior art that Novozymes chose as the target of comparison. The Examiner's interest would have been more than "academic," had her attention ever been called to the variances from Suzuki.

(3) The BSG del Data Omissions

Novozymes misrepresents the evidence again in likening the BSG del measurements omitted from the Borchert Declaration to unequivocally bad measurements obtained after a "scientist drops his sandwich into a test tube." (NZ Opp. at 18.) Novozymes equates Dr. Klibanov's testimony, that it is inappropriate to use measurements taken from a sample into which a sandwich had been dropped (Klibanov, Tr. at 612:14-24, A-6020), with an endorsement of Novozymes' *post-hoc*, post-measurement omission of the 2881 minute measurements, when he quite vehemently disagreed with the omission. (Klibanov, Tr. at 577:22-578:16, A-5808–5809.)

Trying to ignore the cumulative effect of its improper data manipulation in the Borchert Declaration, Novozymes focuses on the fact that the inclusion of the good measurement (versus the inclusion of both the good and bad measurements) for BSG del at 2940 minutes only caused a "modest change" in the improvement of BSG from the 63-fold stated in the Borchert Declaration, from 55- to 77-fold. (NZ Opp. at 18-19.) But, when the entire data set from the Borchert experiment is taken at face value and appropriately analyzed, then the difference in improvement in BSG versus BAN was "way under a factor of two." (Klibanov, Tr. at 610:9-11, A-6018.) Even taking into account Novozymes' data indicating the half-life of BAN WT to be 0.435 minutes, rather than Dr. Klibanov's estimate of approximately 0.3 minutes, the relative improvement remains less than 3. (GCOR Opp. at 19-21.)

Novozymes' misrepresentations of the data set as a whole resulted in the misrepresentation of the results and the reliability of the Borchert experiment.

C. **Machius '95 Was Highly Material**

None of the evidence summarized by Novozymes in Exhibit A to its Opposition shows that Machius '95 was cumulative or that Mr. Garbell or Dr. Borchert contemporaneously thought Machius '95 to be immaterial to the '031 Patent. (In fact, Novozymes' statements are mostly wrong. (NZ Opp. at

Exhibit A.)) Nor has Novozymes come forth with any credible explanation of why Dr. Borchert and Mr. Garbell did not cite Machius '95. (GCOR Post-Trial Brief at 29-33; GCOR Opp. at 12-16.)

Novozymes asserts that Mr. Garbell "was not in doubt that Machius was immaterial" (NZ Opp. at Exhibit A), contradicting Mr. Garbell's trial testimony that he had made no conscious decision either way about citing Machius '95. (Garbell, Tr. at 444:16-20, A-5675.) Either Mr. Garbell made an affirmative decision not to cite Machius '95, or Mr. Garbell did not make an affirmative decision about whether to cite it. (Garbell, Tr. at 440:23-24, A-5671, 441:14-15, A-5672.) Novozymes has presented no evidence that during the pendency of the '031 Patent application Mr. Garbell considered Machius '95 to be immaterial. Given his admitted inability to fully judge the teachings of Machius '95 and the "when in doubt" rule (Garbell, Tr. at 443:7-14, A-5674) (FF 97), Mr. Garbell should have disclosed Machius '95. Novozymes' contradictory positions regarding Mr. Garbell's consideration (or not) of Machius '95 evidence a "cover up," not good faith conduct.

As to Dr. Borchert's concealment of Machius '95, Novozymes claims that Genencor relies on its counsel's testimony about what was missing in Suzuki, "not what is present in Machius." (NZ Opp. at Exhibit A.) Yet, counsel's questions were virtually literal extractions from Machius '95, and Dr. Borchert did not disagree that these teachings were missing from Suzuki. (Borchert, Tr. at 357:22-360:7, A-5588–5591; compare TE 173 at 553, A-8384). Novozymes' excuse that Dr. Borchert did not "say that anything in Machius is important" (NZ Opp. at Exhibit A) contradicts Dr. Borchert's and Novozymes' statements revealing pre-litigation reliance on Machius '95. (GCOR Opp. at 1-2.)

Novozymes asks the Court to look past Dr. Borchert's litigation about-face, and consider a declaration submitted in an unrelated interference as evidence of good faith regarding his failure to cite Machius '95. (NZ Opp. at 12-14.) The interference dealt with a different issue, whether Machius '95 disclosed the calcium-binding sites of BLA (TE 524 at 13-14, A-8908–8909); this has no bearing on the subject matter of the '031 Patent or the effect of making the Suzuki deletion in a surface loop.

D. **Novozymes' Omissions and Misrepresentations Were Intentionally Deceptive**

Novozymes' Opposition Brief is peppered with references to the lack of direct testimony evidencing Dr. Borchert and Mr. Garbell's deceptive intent. Yet, Dr. Borchert's and Mr. Garbell's actions speak louder than words: they hatched a plan to secure issuance of claims directed to BSG with deletions in residues 179-180 (FF 30-40) and, in the face of intense commercial pressures following the release of SPEZYME® Ethyl, made sure that the plan was speedily executed (FF 41-48), at the expense of a full accounting to the PTO of the most material prior art and the Borchert Declaration's misrepresented "unexpected" and "very surprising" results.

It hardly bears repetition that deceptive intent "need not be proven by direct evidence; it is most often proven by a showing of acts, the natural consequences of which are presumably intended by the actor." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 (Fed. Cir. 1995). When balanced against the high materiality of the withheld Machius '95 and the misrepresentations of the Borchert Declaration, the showing of intent can be proportionately less than when materiality is low. *See Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1381 (Fed. Cir. 2001). Novozymes' extensive reliance on *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988), in its Opposition Brief cannot save it from a finding of inequitable conduct.[15] There, the Federal Circuit reversed a trial court's finding of inequitable conduct due to an attorney's gross negligence in failing to detect a ministerial error that both parties' experts agreed was made without deceptive intent. *See Kingsdown*, 863 F.2d at 872-76.

[15] Novozymes cites to no less than 24 cases on inequitable conduct, all factually or legally inapplicable. For example, with respect to the Borchert Declaration, Novozymes cites to *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003) (NZ Opp. at 10), where the defendant accused the patentee of inequitable conduct for withholding certain results of its experiments, but the Federal Circuit upheld the trial court's decision (*Amgen*, 314 F.3d at 1357-58) that there was no inequitable conduct: those experiments were before the PTO in the record of an interference involving the patent. *See Amgen v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 145-47 (D. Mass. 2001). With respect to Machius '95, Novozymes cites to *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003) (NZ Opp. at 10), where summary judgment of inequitable conduct was reversed because there was no factual analysis of whether the withheld prior art reference was relevant or cumulative to the prior art of record. *Dayco*, 329 F.3d at 1367. In *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991) (NZ Opp. at 11, 14), the Federal Circuit upheld a trial court's finding of no inequitable conduct when the reference in question was a one-paragraph summary of a 27-page article that the patentee had submitted to the Examiner. *Scripps*, 927 F.2d at 1582. All of the cases cited by Novozymes are similarly inapplicable to this case.

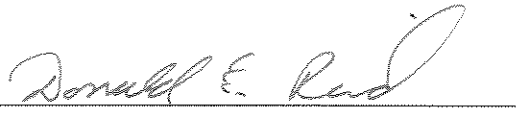
Here, there was no ministerial error nor gross negligence, but a concerted plan to secure the '031 Patent at any cost. Dr. Borchert's and Mr. Garbell's persistent pattern of material omissions and misrepresentations, both in withholding Machius '95 and failing to fairly disclose the bases, outcome, and significance of the Borchert experiment, are tantamount to clear and convincing evidence of their deceptive intent. *See PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1320 (Fed. Cir. 2000). (GCOR Opp. at 16-26 and citations; CL 85-86.)

Implementing its "option" plan, Novozymes deliberately reached back to a rejection no longer pending, telling the PTO that it was entitled to claims based on "unexpected" results compared to Suzuki. The results were not unexpected, they were not a fair comparison to Suzuki, and they did not address the concealed but closest prior art, Machius '95. Dr. Borchert and Mr. Garbell knew this, knew it mattered, and concealed it from the PTO. The fruit of their plan is rotten: the '031 Patent is unenforceable.

VI. CONCLUSION

The '031 Patent should never have issued, much less been asserted in litigation. The winner in the marketplace should be decided there, not in this Court. Genencor is entitled to judgment of non-infringement, invalidity, and unenforceability of the '031 Patent, and to its attorneys fees in this case.

MORRIS, NICHOLS, ARSHT & TUNNELL



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May 12, 2006

EXHIBIT A

Genencor's Response to Novozymes' Exhibit A

The Accusation	*The Facts (According to Novozymes)*	*The Truth*
Garbell recognized that Machius at least summarized Suzuki. **GPTB, at 32.**	True. This is the essence of a cumulative reference. *Scripps.*, 927 F.2d at 1582. And Garbell thought there was nothing material in Machius. **A5671:23-5672:17.**	Summarizing the disclosed art, enhancing motivation and adding directly relevant structural teachings on which Novozymes had relied for years, is hardly cumulative. **FF 93; CL 92-93.**
Garbell admitted it was possible the '031 patent would not have issued had Machius been cited. **GPTB, at 31.**	False. Garbell agreed that if the Examiner rejected the claims over Machius, it is "possible" that patent might not have issued; but he did not know. **A5676:9-14.**	Isn't that the point? Novozymes knew disclosure of Machius '95 risked a rejection to which it had no response. **FF 98; CL 89-93.**
Garbell knew of and violated the "when in doubt rule" about citing prior art. **GPTB, at 32.**	False. Garbell was not in doubt that Machius was immaterial. **A5676:25-A5677:4.**	Novozymes misrepresents this testimony. It simply does not say Garbell thought Machius '95 was immaterial. Garbell testified that he never even considered disclosing Machius '95, nor was he qualified to make the decision. **FF 91-93, 95-98; CL 88-93.**
Borchert admitted that Machius contained teachings beyond those of Suzuki. **GPTB, at 32.**	False. The cited testimony refers to what Genencor's counsel alleged was missing in Suzuki, not what is present in Machius. Nor did Borchert say that anything in Machius is important. **A5588:22-5589:25; NPF, ¶393-401.**	Is it really necessary to point out, again, that Machius '95 discloses exactly those items Dr. Borchert admitted were not in Suzuki? Of course, Dr. Borchert did not admit in court that those teachings were "important," yet he admitted the differences from Suzuki and repeatedly relied on Machius '95 in lectures, papers, and before the PTO. **FF 75-76, 86-90; CL 90-91.**
Novozymes decided not to cite Machius to ensure that the '031 patent would issue because of "new grounds" for rejection which would have presented "uncertain obstacles" or at least delayed issuance of the '031 patent. **GPTB, at 32-33.**	False. Novozymes knew about Machius for 10 years; there was time to cite it. **NPF, ¶249-56; GPTB, at 30.** Nor did Machius become material at the last minute. It provided no new ground for rejection. **NPF, ¶249-56, 393-401.** Machius was not cited because it was not seen as material. **NPF, ¶249-56, 393-401.**	None of the indirect evidence cited by Novozymes establishes that Novozymes did not cite Machius '95 because it was not seen as material. Rather, Mr. Garbell did not even consider the issue and Dr. Borchert chose to ignore Machius '95 in the '031 Patent prosecution after 10 years of relying on it. **CL 91, 93-94.**

EXHIBIT A

Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States Court of Appeals,Federal Circuit.

LAVA TRADING, INC, Plaintiff-Appellant,

v.

SONIC TRADING MANAGEMENT, LLC, Joseph Cammarata, and Louis Feng Liu, Defendants-Appellees,

andRoyalblue Group PLC, Royalblue Financial Corporation And Royalblue Financial PLC, Defendants-Appellees.

Nos. 05-1177, 05-1192.

April 19, 2006.

Background: Patent holder brought action alleging infringement of patent for software that aggregated and integrated securities trading and order placement information from various alternative trading systems. Defendants counterclaimed for declaratory judgment that patent was invalid and not infringed. The United States District Court for the Southern District of New York, Thomas P. Griesa, J., issued claim construction ruling from bench, and the parties stipulated to final judgments of non-infringement. Holder appealed.

9**Holding:** The Court of Appeals, Rader, Circuit Judge, held that the claim construction was flawed.

Vacated and remanded.

Mayer, Circuit Judge, dissented and filed opinion.

[1] **Patents 291 324.2**

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k324 Appeal
291k324.2 k. Decisions Reviewable. Most Cited Cases

Court of Appeals had jurisdiction over appeal from stipulated judgment of non-infringement of patent, even though defendants' counterclaims of invalidity and unenforceability were still pending before the trial court and the record did not supply any meaningful comparison of the accused products to the asserted claims; district court had certified judgment as final. 28 U.S.C.A. § 1295(a)(1); Fed.Rules Civ.Proc.Rule 54(b), 28 U.S.C.A.

[2] **Federal Courts 170B 660.20**

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(E) Proceedings for Transfer of Case
170Bk660 Certification and Leave to Appeal
170Bk660.20 k. Multiple Claims. Most Cited Cases

Rule on final judgment as to fewer than all claims or parties allows a district court to act as a dispatcher and determine, in the first instance, the appropriate time when each final decision upon one or more but fewer than all of the claims in a multiple claims action is ready for appeal. Fed.Rules Civ.Proc.Rule 54(b), 28 U.S.C.A.

[3] **Patents 291 226.6**

291 Patents
291XII Infringement
291XII(A) What Constitutes Infringement
291k226.5 Substantial Identity of Subject Matter
291k226.6 k. Comparison with Claims of Patent. Most Cited Cases

An infringement analysis is a two-step process: (1) the court determines the scope and meaning of the patent claims asserted, and (2) the properly construed claims are compared to the allegedly infringing device.

[4] **Patents 291 324.5**

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k324 Appeal
291k324.5 k. Scope and Extent of Review in General. Most Cited Cases

Claim construction of a patent is a question of law reviewed de novo.

[5] **Patents 291 226.6**

291 Patents
291XII Infringement

291XII(A) What Constitutes Infringement
291k226.5 Substantial Identity of Subject Matter
291k226.6 k. Comparison with Claims of Patent. Most Cited Cases

Patents 291 314(5)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k314 Hearing
291k314(5) k. Questions of Law or Fact. Most Cited Cases
Comparison of patent claims to the accused device is a question of fact and requires a determination that every claim limitation or its equivalent be found in the accused device.

[6] **Patents 291 324.1**

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k324 Appeal
291k324.1 k. In General. Most Cited Cases
Change in patent holder's claim construction theory from original hearing to motion for reconsideration and appeal did not result in waiver of theory on appeal; patent claimed software that aggregated and integrated securities trading and order placement information from various alternative trading systems, the holder originally argued that the term "distributing" involved one security, but later argued for application to one security or more than one security, and the slight change in the theory did not result in any meaningful change in the alleged infringers' position or evidence relied upon at the trial court or on appeal.

[7] **Estoppel 156 68(2)**

156 Estoppel
156III Equitable Estoppel
156III(B) Grounds of Estoppel
156k68 Claim or Position in Judicial Proceedings
156k68(2) k. Claim Inconsistent with Previous Claim or Position in General. Most Cited Cases
Judicial estoppel does not normally apply on appeal to prevent a party from altering an unsuccessful position before the trial court.

[8] **Estoppel 156 68(2)**

156 Estoppel
156III Equitable Estoppel
156III(B) Grounds of Estoppel
156k68 Claim or Position in Judicial Proceedings
156k68(2) k. Claim Inconsistent with Previous Claim or Position in General. Most Cited Cases
Judicial estoppel would not bar patent holder from departing from a claim construction theory unsuccessfully advocated before the trial court.

[9] **Patents 291 101(2)**

291 Patents
291IV Applications and Proceedings Thereon
291k101 Claims
291k101(2) k. Construction in General. Most Cited Cases
Patent claim which involved a data processing method for providing trading information to traders in a security or commodity from two or more alternative trading systems and comprised steps of distributing and displaying the combined order book to the traders did not require the system to distribute or display the whole combined order book; specification disclosed embodiments that distributed and displayed information for only a subset of the combined order book, and one of ordinary skill in the art would construe the distributing and displaying limitations as covering an embodiment that distributes and displays information for only a subset of the combined order book.

[10] **Patents 291 314(1)**

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k314 Hearing
291k314(1) k. In General. Most Cited Cases
A district court retains discretion to rule from the bench at close of *Markman* hearing without issuing a formal claim construction order.

Patents 291 328(2)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated

291k328(2) k. Original Utility. Most Cited Cases
6,278,982. Construed.

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Before MAYER, RADER, and LINN, Circuit Judges.

Opinion for the court filed by Circuit Judge RADER. Dissenting opinion filed by Circuit Judge MAYER.RADER, Circuit Judge.

***1** This appeal stems from two stipulated judgments of non-infringement of U.S. Patent No. 6,278,982 (the '982 patent). *Lava Trading, Inc. v. Sonic Trading Mgmt., LLC,* 03-CV-9382 (S.D.N.Y. Dec. 8, 2004) (*Royalblue Stipulation*); *Lava Trading, Inc. v. Sonic Trading Mgmt., LLC,* 03-CV-0842 (S.D.N.Y. Dec. 8, 2004) (*Sonic Stipulation*). Because flaws in the district court's interpretation of claim 9 call the stipulated judgments into question, this court vacates and remands for further proceedings.

I.

Lava Trading, Inc. (Lava) owns the '982 patent, which claims software that aggregates and integrates securities trading and order placement information from various alternative trading systems. '982 patent, col. 1, ll. 7-13. Lava sued Sonic Trading Management LLC, Joseph Cammarata and Louis Feng Liu (collectively Sonic) and Royalblue group plc, Royalblue financial corporation and Royalblue financial plc (collectively Royalblue) in the United States District Court for the Southern District of New York for infringement of the '982 patent, among other state law claims. The defendants denied infringement and counterclaimed for a declaratory judgment that the '982 patent is invalid, unenforceable, and not infringed. *Royalblue Stipulation,* slip op. at 1; *Sonic Stipulation,* slip op. at 1.

On May 24-26, 2005, the district court held a *Markman* hearing and issued a claim construction ruling from the bench. Thereafter, the parties stipulated to final judgments of non-infringement. *See Royalblue Stipulation; Sonic Stipulation.* Lava appeals the stipulated final judgment orders.

II.

[1] At the onset, the procedural posture of this appeal presents problems. For instance, this court notes that defendants' counterclaims of invalidity and unenforceability are still pending before the trial court. These pending counterclaims put this court in the awkward position of reviewing a claim construction that may implicate issues and claims beyond this court's current reach. *See Int'l Commc'n Materials, Inc. v. Ricoh Co.,* 108 F.3d 316, 318-19 (Fed.Cir.1997) (commenting that, when substantial issues remain open on appeal, this court should first "provide the district judge and parties the opportunity to complete the picture.").

In addition, this record on appeal does not supply any meaningful comparison of the accused products to the asserted claims. Without knowledge of the accused products, this court cannot assess the accuracy of the infringement judgment under review and lacks a proper context for an accurate claim construction. "While a trial court should certainly not prejudge the ultimate infringement analysis by construing claims with an aim to include or exclude an accused product or process, knowledge of that product or process provides meaningful context for the first step of the infringement analysis, claim construction." *Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.,* 442 F.3d 1322 (Fed.Cir.2006) (citing *SRI Int'l v. Matsushita Elec. Corp. of Am.,* 775 F.2d 1107, 1118 (Fed.Cir.1985); *Scripps Clinic & Research Found. v. Genentech, Inc.,* 927 F.2d 1565, 1580 (Fed.Cir.1991); *Multiform Desiccants, Inc. v. Medzam, Ltd.,* 133 F.3d 1473, 1476-78 (Fed.Cir.1998); *Pall Corp. v. Hemasure Inc.,* 181 F.3d 1305, 1308 (Fed.Cir.1999)). Without the vital contextual knowledge of the accused products or processes, this appeal takes on the attributes of something akin to an advisory opinion on the scope of the '982 patent. The problems with such an appeal, even if within this court's jurisdiction, have been noted in many of the court's prior cases. *See, e.g., id.* (citing *Bayer AG, v. Biovail Corp.,* 279 F.3d 1340, 1349 (Fed.Cir.2002); *CVI/Beta Ventures Inc. v. Tura LP,* 112 F.3d 1146, 1160 n. 7 (Fed.Cir.1997)).

***2** [2] Nonetheless, the court notes that the district court issued a Rule 54(b) certification in this case. *See* Fed.R.Civ.P. 54(b). Rule 54(b) allows a district court to act as a "dispatcher" and "determine, in the first instance, the appropriate time when each 'final decision' upon 'one or more but less than all' of the claims in a multiple claims action is ready for appeal." *Pause Tech. LLC. v. TiVo Inc.*, 401 F.3d 1290, 1294 n. 2 (Fed.Cir.2005). Thus, while troubled by the pending counterclaims and the absence of a detailed infringement analysis, this court has jurisdiction under 28 U.S.C. § 1295(a)(1) (2000).

III.

Turning to infringement, the '982 patent claims software that aggregates and integrates information from various systems for buying and selling securities (e.g., stocks, bonds, commodities and derivatives). *See* '982 patent, col. 1, ll. 7-13. The '982 patent specifically addresses a problem wherein a user with access to only a subset of these systems confronts substantial fluctuations in prices amongst these systems for a given security. *Id.* at col. 3, ll. 6-31. To illustrate, a buyer may not know of lower prices available on another system and/or a seller may not know of higher prices available on another system.

Embodiments of the '982 patent solve this problem by aggregating and integrating information from these various systems. One embodiment of the '982 patent depicted in Figure 5, for example, aggregates and integrates pricing data for a single security (e.g., DELL):

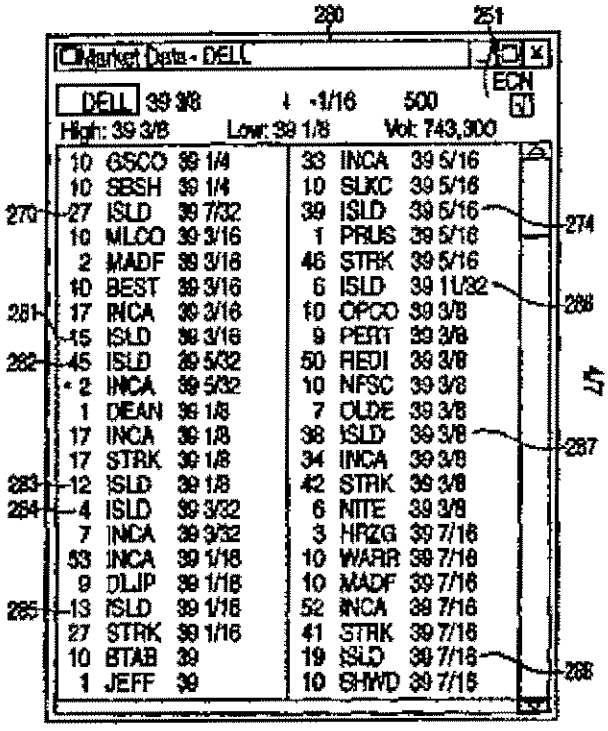

FIG. 5

Id. at col. 9, ll. 9-25. As shown above, the screen 280 "provides the customer with the ability to take advantage of price variations in a rapidly changing environment." *Id.* at col. 9, ll. 23-25. Thus, the user is provided with considerable pricing information for a given security and, armed with this information, can make a transaction. The patent also discloses other embodiments.

[3][4][5] With this backdrop, an infringement analysis is a two-step process: "First, the court determines the scope and meaning of the patent claims asserted ... [and second,] the properly construed claims are compared to the allegedly infringing device." *Cybor Corp.*, 138 F.3d at 1454 (citations omitted). "Step one, claim construction, is a question of law, that we review de novo. Step two, comparison of the claims to

the accused device, is a question of fact, and requires a determination that every claim limitation or its equivalent be found in the accused device." *N. Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1344 (Fed.Cir.2005) (citations omitted).

A. Waiver/Estoppel

[6] Before this court can construe the claims, however, it must first address a potential waiver/estoppel issue surrounding Lava's current claim construction theory. The waiver/estoppel issue relates to a change in Lava's counsel during proceedings before the district court. Before and during the district court's *Markman* hearing(s), Lava's initial counsel argued the term "distributing" should be construed as "providing the consolidated or composite single list of open orders for a *given security* ... to the users of the present invention"-i.e., for only *one* security. *Pl. Lava Trading Inc.'s Opening Claim Constr. Br.* at 53, *Lava Trading Inc. v. Sonic Mgmt., LLC*, 03-CV-842 & 03-CV-9382 (S.D.N.Y.2003) (emphasis in original altered). The district court, however, rejected Lava's proposed definition and adopted a construction requiring the distribution of data for *all* securities in the combined order book. *Lava Trading, Inc. v. Sonic Trading Mgmt., LLC*, 03-CV-9382 & 03-CV-0842, slip op. at 442-43 (S.D.N.Y. Dec. 8, 2004) (*Claim Construction Order*). Lava then obtained new counsel who advanced Lava's current claim construction theory in a motion for reconsideration. Lava now interprets "distributing" as "providing to traders combined order book information ... for *one security or more than one security,* as desired by the traders"-i.e., a *subset* of the combined order book. *Memorandum In Support Of Lava's Motion For Reconsideration Of A Portion Of The Court's Decision On Claim Constr.* at 2, *Lava Trading, Inc. v. Sonic Trading Mgmt., LLC*, 03-CV-842 & 03-CV-9382 (S.D.N.Y. July 29, 2004) (emphasis added). The district court rejected Lava's motion for reconsideration without comment. *Lava Trading, Inc. v. Sonic Trading Mgmt., LLC*, 03-CV-842 & 03-CV-9382 (S.D.N.Y. Aug. 10, 2004).

***3** Seizing on this change in Lava's claim construction theory, the defendants argue that Lava has waived its current theory and should be estopped from raising it on appeal. The defendants rely on cases in which a party presented an argument on appeal that substantially changed the scope of a prior position taken before a trial court. *See, e.g., NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1296 (Fed.Cir.2005) (waiver applied because RIM attempted to add a pull technology limitation to the claim that it did not raise before the trial court); *SuperGuide Corp. v. DirecTV Enter., Inc.*, 358 F.3d 870, 889 (Fed.Cir.2004) (waiver applied because SuperGuide stipulated to construction of the term "meet" at the trial court); *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1363 (Fed.Cir.1999) (waiver applied because Finnigan's petition to the Commission did not point out the relevance of the lack of the term "unstable" in claim 17); *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1426 (Fed.Cir.1997) (waiver applied because Sage did not present its construction of "elongated slot" to the trial court). Upon review, the court concludes these cases do not govern the facts of this case.

[7][8] At the outset, judicial estoppel does not normally apply on appeal to prevent a party from altering an unsuccessful position before the trial court. *See RF Del., Inc. v. Pacific Keystone Tech., Inc.*, 326 F.3d 1255, 1262 (Fed.Cir.2003) (quoting *Data Gen. Corp. v. Johnson*, 78 F.3d 1556, 1565 (Fed.Cir.1996)) ("The doctrine of judicial estoppel is that where a party *successfully* urges a particular position in a legal proceeding, it is estopped from taking a contrary position in a subsequent proceeding where its interests have changed.") (emphasis in original). Thus, estoppel would not bar Lava from departing from a claim construction theory unsuccessfully advocated before the trial court.

Moreover, on the limited record on appeal, this court cannot discern any practical difference between Lava's two theories. In response to both theories, the defendants counter that the intrinsic record limits the claims to a system that distributes and displays information for *all* securities. Thus, the slight change in Lava's theory has not resulted in any meaningful change in the defendants' position or evidence relied upon by the defendants at the trial court or on appeal. The absence of any practical differences in the case reinforces this court's determination that Lava has not waived its current theory. *See Harris Corp. v. Ericsson Inc.*, 417 F.3d 1241, 1252 (Fed.Cir.2005) (waiver did not apply because the technical distinction in Ericsson's argument did not make any practical difference in the case).

B. The Disputed Limitations

[9][10] On the merits, the parties dispute the meaning of two related limitations in the '982 patent, "distributing" and "displaying" a combined order book to a trader. Independent claim 9 recites both limitations:

***4** 9. A data processing method for providing trading information to traders in a security or commodity from two or more alternative trading systems, comprising the steps of:
receiving order book information from each participating alternative trading system in order book information protocols native to the particular alternative trading system;
converting the information to a common system order book protocol;
integrating the order book information from each alternative trading system into a single order book;
distributing the combined order book to the traders in the common system order book protocol; and
displaying said combined order book to the traders.

'982 patent, col. 14, ll. 1-14 (emphasis added). The district court construed the disputed limitations during a *Markman* hearing without issuing a formal claim construction order. Instead, the district court stated its claim construction from the bench at the close of the hearing. A district court retains discretion to rule in this manner, but in this instance the trial court's oral recitation provides a very sparse explanation of the findings and reasoning supporting the claim construction.

Regarding the distributing limitation, the district court concluded that it "simply means distributing the combined order book-that means in terms of the specification the consolidated order book-pertaining to all orders from all ECN members." *Claim Construction Order* at 442-43. In other words, the distributing limitation requires the distribution of the whole combined order book to the trader. The district court similarly construed the displaying limitation, concluding the system must display the whole combined order book for the trader. Upon review, the district court's interpretation of the "distributing" and "displaying" limitations conflicts with the plain meaning of claim 9 and excludes embodiments disclosed in the specification.

According to its preamble, claim 9 "provid[es] trading information to traders in *a security or commodity* " rather than "all" securities or commodities. '982 patent, col. 14, ll. 1-2 (emphasis added). By selecting the word "a" instead of "all," the Applicant set forth a method wherein the traders may request and receive information for only a subset of the securities (i.e., one or more). *See KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed.Cir.2000) (the word "a" generally means "one or more" in open-ended claims). Thus, the language of the claim itself does not require the system to distribute or display the whole combined order book.

Furthermore, the specification discloses embodiments that distribute and display information for only a subset of the combined order book. As an example, the specification describes one embodiment in which
the CCS 100 collects orders from each ECN, (ECN150 and ECN251) and electronic exchanges (NASDAQ 52), distributes a composite order book to the customers according to each customer's memberships in the ECNs and rights to use an electronic exchange. *Thus customer 10 may only receive a subset of the complete order book* compiled by the CCS 100 corresponding to where the customer 10 is permissioned.

***5** '982 patent, col. 6, ll. 59-66 (emphasis added). According to this embodiment the customer only receives a "subset" of the combined/complete order book from the system. Thus, this embodiment must also make the system capable of "distributing" less than the whole combined order book *to* the customer-i.e., a subset of the combined order book.

The specification also discloses an embodiment in which bid and offer prices for Dell, a single security, are displayed on a market data screen:
Fig. 4 depicts a typical market data screen 250 of the present invention. Such screens can be customized as to data or order to conform to the customer's trading style. ... The security under review is Dell Computer Corp. It was elected by inserting its ticker symbol DELL in space 252.

'982 patent, col. 8, ll. 47-54. This embodiment is further described in reference to Figure 5:FIG. 5 shows pricing data that would be available to a customer of the present invention. Here, space 251 has been checked on screen 280 and ECN information integrated into the display. Screen 280 shows not only NASDAQ Level II data but also the full order book for the following three ECNs: Instinet, Island and Strike. For these ECN's, there are multiple bids and offers available for DELL, as opposed to just the best bid and offer.... Screen 280, thus, offers access to a greater amount of pricing information (thus greater liquidity), consolidated in one display. Thus, the entire order books of all ECN members and the market makers' bids and offers are consolidated into a single informative screen for any particular security. This additionally provides the customer with the ability to take advantage of price variations in a rapidly changing environment.

Id. at col. 9, ll. 9-25. Hence, the specification discloses

embodiments that distribute and display information for only a subset of the securities (e.g., one in the embodiment of Figures 4 and 5) in the combined order book.

Reading the claim language and these embodiments in the specification, one of ordinary skill in this art would not limit the distributing and displaying limitations in the manner suggested by the district court. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed.Cir.2005) (*en banc*) ("Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification."). Rather, one of ordinary skill in the art would construe the distributing and displaying limitations as covering an embodiment that distributes and displays information for only a subset of the combined order book.

For at least these reasons, this court sets aside the district court's claim construction. Because the final judgment orders are premised on the flawed claim construction, they too must be set aside. The case is remanded to the district court for further proceedings consistent with this opinion.

COSTS

***6** Each party shall bear its own costs.

VACATED and REMANDED

MAYER, Circuit Judge, dissenting.
Because there was no final judgment from which to appeal in the district court due to the interrelatedness of the infringement claim and the unresolved unenforceability counterclaim, I would dismiss this case for lack of jurisdiction. Therefore, I dissent.

The decision today is yet another example of the unfortunate consequences of *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed.Cir.1995) (en banc), *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448 (Fed.Cir.1998) (en banc), and *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed.Cir.2005) (en banc), which cemented this court's jurisprudence with respect to claim construction as being purely a matter of law subject to de novo review. Because claim construction is treated as a matter of law chimerically devoid of underlying factual determinations, there are no "facts" on the record to prevent parties from presenting claim construction one way in the trial court and in an entirely different way in this court. By not dismissing this case, we issue a decision based on an undeveloped record. We set ourselves up to have to decide claim construction again later, which could well differ from the ruling today. Furthermore, allowance of an appeal of the trial court's perfunctory, offhand ruling from the bench, for all intents and purposes allows an interlocutory appeal of claim construction, which portends chaos in process.

FN1. While NASDAQ information comes from a particular electronic exchange rather than an alternative trading system, claim 9 is an open-ended claim that encompasses more than simply information from alternative trading systems. *See* U.S. Patent No. 6,278,982, col. 2, ll. 16-29, col. 14, l. 3.

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CERTIFICATE OF SERVICE

I, Donald E. Reid, hereby certify that on the 12th day of May, 2006 Defendants' Rebuttal Post-Trial Brief was served by electronic filing upon counsel of record:

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